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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,266	01/17/2002	Ernst Heinz	VOS-29	1286
1473	7590	04/24/2006		
FISH & NEAVE IP GROUP ROPES & GRAY LLP 1251 AVENUE OF THE AMERICAS FL C3 NEW YORK, NY 10020-1105				EXAMINER HELMER, GEORGIA L
				ART UNIT 1638 PAPER NUMBER

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/053,266	HEINZ ET AL.	
	Examiner	Art Unit	
	Georgia Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 January 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 4-23 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1 and 4-23 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 January 2006 has been entered.

Status of the Claims

2. Claims 1 and 4-23 are pending, and are examined in the instant action.
3. All rejections not addressed below have been withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112 Enablement

5. Claims 1 and 4-23 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of generating transgenic *Linum usitatissimum* (flax) plant cells comprising introducing *Agrobacterium tumefaciens* containing vector bearing a neomycin phosphotransferase gene which confers resistance to kanamycin and to G418 to hypocotyl segments, by coculturing for 4 days, transfer of cocultured material to medium containing a combination of NAA, benzylaminopurine, and kanamycin for 6 weeks, followed by transferring selected calli or shoot material to medium containing a second antibiotic, G418, and rooting selected calli or shoots to produce a whole plant, as described in the specification (pages 20,

Art Unit: 1638

Example 2, through page 28), does not reasonably provide enablement for the broad scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The advisory action of 22 November 2005 rejected claims 1 and 4-23, noting that "all the references cited by the Applicant in the After Final Amendment support the Examiner 's position that the use of Agrobacterium tumefaciens transformation of flax hypocotyls were both required for high efficiency transformation and normal morphology".

Applicant's arguments filed 28 June 2005 and 30 January 2006 have been fully considered, but are not deemed persuasive.

Applicant traverses saying the references cited in the After Final Amendment: Bretagne-Sagnard et. al., 1996; McHughen & Jordan, 1989, Plant Cells Report, vol. 7, pages 611-614; Zahn, et al, Plant Molecular Biology, 1988, vol 11, pages 551-559.; and Ling, Versuche fur Entwicklungsbiologie und somatische Genetik in vitro mit Arten der Gattung Linum. Dissertation des Doctorgrades, in der Mathematisch-Naturwissenschaftlichen Facultat der Christian Albrechts-Universitat zu Kiel (1997), "demonstrate that skilled artisans were, at the filing date are able to employ various approaches to achieving flax transformation". Applicants further traverse " the claims can be practiced to the full scope without undue experimentation, regardless of whether the results that are achieved meet an arbitrary threshold of efficiency and morphological characteristics. The Examiner appears to have improperly imported such a threshold

Art Unit: 1638

limitation into the claims...[I]t is reasonable to expect that most or all methods of flax transformation will benefit from the claimed inventions because the specification provides numerous working examples with different genetic backgrounds." (Response of 30 January 2006, p. 6-7).

Applicant's traversal is unpersuasive. The references cited by the Applicant in the After Final Amendment: Bretagne-Sagnard et. al., 1996, McHughen et al, 1989; Zahn et al, 1997; and Ling, 1988, which Applicant "says demonstrate enablement for more than just transformation with *Agrobacterium tumefaciens*", are used in the specification to demonstrate the difficulties of the state of the art at the time of filing. See the conclusionary statement "Hence, the production of flax primary transformants, if at all possible, seemed to be genotype-dependent, time-consuming and/or resulting initially in plants with aberrant morphology" (specification p.2), emphasis added. The specification continues: "Thus the technical problem underlying the present invention is to provide a reliable and efficient method for the generation and selection of stable transformed plant of the genus *Linum*."

- Furthermore, Bretagne-Sagnard et. al. teach the use of *Agrobacterium tumefaciens* to transform flax hypocotyls but indicate that the use of "different neomycins for the selection of transformed tissues did select transformed calli but not transformed shoots either directly or via a callus phase. Selection based on spectinomycin ...allowed the growth of transformed shoots", and "[t] herefore spectinomycin is a more suitable for genetic engineering of flax than animoglycoside resistance". See Abstract p. 131.

Art Unit: 1638

- McHughen & Jordan, 1989, used *Agrobacterium tumefaciens* to infect flax hypocotyls and selection on kanamycin, showing that “escape” regenerants may contain stable transgenic cells which may be rescued using a second cycle of regeneration or by testing a larger number of progeny. Only hypocotyls of flax were studied by McHughen et al.
- Ling, 1997, using a protoplast transformation system, which, compared to the hypocotyl method, “produced significantly fewer plants, and those that were produced often exhibited morphological abnormalities” (specification p. 2).
- Zahn, et al, 1988, studied *Agrobacterium rhizogenes*-infected flax cotyledons, which produced only transgenic plantlets having curled leaves, short internodes and ...root systems “characterized by plagiotropic behavior”. See p. 551, abstract. Plagiotropic means having a longer axis inclined away from the vertical.
- US 5,973,227, issued 26 October 1999, and cited by the Applicant (Response of 28 June 2005, p. 8), describes transformation of flax hypocotyls by particle bombardment. However, US 5,973,227 issued 26 October 1999, and was not available as of the filing date of the instant case, 20 July 1999. See *In re Glass*, 181 USPQ 31, 34 (CCPA 1974), which teaches that references published after the filing date of an application may not be relied upon for the enablement of the specification.

Therefore Applicant's cited references support the Examiner's position that

Art Unit: 1638

"the use of *Agrobacterium tumefaciens* transformation of flax hypocotyls were both required for high efficiency transformation and normal morphology".

Applicant traverses primarily "it is reasonable to expect that most or all methods of flax transformation will benefit from the claimed inventions because the specification provides numerous working examples with different genetic backgrounds." (Response of 30 January 2006, p. 7).

Applicant's traversal is unpersuasive. The specification provides evidence for the use of the *Agrobacterium tumefaciens* transformation of the single flax variety "Flanders" in the invention (p. 25-27, Examples 4-6). Reference is made to two other flax varieties "McGregor and Ed 45" (p. 19, Table 1), however this table is a dose response curve for the antibiotic G-418.

Applicant traverses primarily that "at the time of filing ...flax transformation techniques were known, and such techniques varied in terms of the mode of transformation (different *Agrobacterium* strains, protoplasts, projectiles), choice of selectable marker (kanamycin, G418, spectinomycin) and target tissue (cotyledon, hypocotyl)". See response filed 28 June 2005, p. 8.

Applicant's traversal is unpersuasive. The Applicant's cited references support the Examiner's position that "the use of *Agrobacterium tumefaciens* transformation of flax hypocotyls were both required for high efficiency transformation and normal morphology".

Furthermore, US 5,973,227, issued 26 October 1999, and cited by the Applicant (Response of 28 June 2005, p. 8), describes transformation of flax hypocotyls by

particle bombardment. However, US 5,973,227 issued 26 October 1999, and was not available as of the filing date of the instant case, 20 July 1999.

Even if the US 5,973,227 disclosure were available as of the date of filing of the instant case, it is the instant specification that should be enabling, not the prior art. Furthermore, the mere germ of an idea does not constitute an enabling disclosure, and the specification, not the knowledge of one skilled in the art must supply the enabling aspects of the invention. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2nd 1001, 1005 (Fed. Cir. 1997).

Furthermore, the US 5,973,227 patent presents numerous modifications and requirements for successful microprojectile transformation of flax. These modifications and requirements are absent from the instant specification. For example, use of "flax hypocotyl tissue comprising epidermal tissue" (claim 1) and preculturing the hypocotyl tissue for a period of 4 days on a medium consisting of 3% sucrose, 0.8% agar, 1.0 mg/l/L BA and 0.02 mg/L NAA (column 4, lines 45-53).

6. Claims 1 and 4-23 remain rejected under 35 U.S.C. 112, first paragraph, for reasons of record in the Office Action of 26 May 2004, because no single claim contains all essential elements of the invention. The essential elements include Agrobacterium transformation, use of selectable marker wherein the DNA confers resistance to a first and a second antibiotic, wherein the second antibiotic is different from the first antibiotic, wherein the antibiotics are selected from the group consisting of kanamycin, paromycin, neomycin, gentamycin, G-418, streptomycin, spectinomycin and imidazole.

Art Unit: 1638

Claims 22 and 23, drawn to a transgenic *Linum usitatissimum* cells, callus tissue or plant of claim 1; or a harvest part of said *Linum usitatissimum*, are rejected because the method of claim 1 is not enabled.

Remarks

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on 10-6 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer
Patent Examiner
Art Unit 1638
April 17, 2006

DAVID T. FOX
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